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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,544	03/01/2004	Miroslav Colic	4904-4DIV	9685
7590 COHEN, PONTANI, LIEBERMAN & PAVANE Suite 1210 551 Fifth Avenue New York, NY 10176			EXAMINER XIE, XIAOZHEN	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/26/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/790,544	COLIC, MIROSLAV	
	Examiner Xiaozhen Xie	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 November 2006.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 15-23 is/are pending in the application.  
 4a) Of the above claim(s) 20 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 15-19 and 21-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>20040301,20050429</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Status of Application, Amendments, And/Or Claims***

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1646, Examiner: Xiaozhen Xie.

The Information Disclosure Statement (IDS) filed 1 March 2004 and 29 April 2005 has been entered in full.

***Election/Restrictions***

The Requirement for Election dated 10 October 2006 requires Applicant to choose one or a specific combination of more than one species listed in claims 19-21. Applicant has elected species of "pro-oxidant metal complexes" and "IL-12" (a cytokine), in the response received 13 November 2006. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-14 have been cancelled. Claims 15-23 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 15-19 and 21-23 are under examination to the extent they read on elected species.

***Specification***

The disclosure is objected to because of the following informalities:

The instant application claims the priority of Application No: 09/640,218 (08/16/2000) (ABN) which claims the benefit of 60/149,131 (08/16/1999). The first line of the specification should include updated cross-reference to related applications. See 37 CFR 1.78 and MPEP § 201.11.

Correction is required.

#### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### ***Claim Objections***

Claim 21 is objected to because of the following informalities: Claim 21 has a grammar error for the recitation of "wherein the cytokines is". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a lung cancer and a colorectal cancer, in a patient comprising administering to the patient a pharmaceutical composition comprising a zeolite that has a mean particle size of 250 nm, does not reasonably provide enablement for treating any type pf cancer, nor by administering zeolite of any sizes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The independent claim 15 recites a method of treating cancer in a patient comprising administering to the patient a pharmaceutical composition comprising a zeolite. The claim is broad in that it encompasses treating any type of cancer by administering any zeolite, i.e., zeolites of any sizes. The specification discloses the synthesis and uses of submicron and nanosized zeolite powders, e.g., clinoptilolite with a mean particle size of 250 nm. The specification teaches three different uses of the nano-engineered zeolite (pp. 25, line 19 to pp. 26, line 8). 1) The nano-engineered zeolite can be used to encapsulate metal complexes that act as an antioxidants or prooxidants (catalytic salen-metal antioxidants or prooxidants with cobalt, maneganeses, ion, rhodium and palladium) (Example I), and exhibit anti-cancer activity in cultures cells and in animal tests using lung, colorectal, breast and melanoma cancer models (Example IV). In such case, tissues or cells need in direct contact with the nano-engineered catalytic salen-metal antioxidants encaptured zeolite. 2) The specification also teaches that clinoptilolite with a mean particle size of 250 nm can be used as a

vaccine adjuvant to enhance the immunogeneity of proteins, cell parts or whole cell vaccines. In such case, the clinoptilolite was injected near the tumor site to attract lymphocytes, and significant infiltration of lymphocytes and tumor remission were observed with melanoma, adenocarcinomas of lung and colorectal models. 3) The specification also teaches that the zeolite can be used to incorporate small drugs, macromolecules or whole cells for a delayed sustained release. Applicant, however, has not provided sufficient teachings to treat any types of cancer, for example, how to treat a non-tumor type of cancer, e.g., leukemia, and how to treat a brain tumor that is inoperable in which injection of the zeolite is impossible? Cancer encompasses neoplasm with many causes, striking many tissues, and with many different outcomes. Thus, the scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification.

Further, the claim encompasses the use of any zeolite of any sizes. Pavelic (J. Cancer Res. Clin. Oncol., 2002, 128:37-44) teaches that zeolites are extensively used in different industrial applications, and zeolites have properties to act as catalysts, ion-exchangers, adsorbents, and detergent builders (pp. 37, Introduction). The specification also describes that despite very potent and catalytic activities, their internal therapeutic applications have been limited due to poor adsorption of large micro sized particles into the body and the risk of side effects (pp. 3, 2<sup>nd</sup> paragraph, and pp. 10, 1<sup>st</sup> paragraph). The specification teaches that particles even larger than 5 microns will sediment from a suspension (pp. 11, last paragraph). The specification has not provided sufficient

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teaching as to how to use any zeolite including micron sized insoluble particles to inject into an animal or human body for the treatment of a cancer. Without any guidance or working example from the specification, the artisan would not know how to practice the invention without undue experimentation.

Due to the large quantity of experimentation necessary to generate indefinite types of zeolites with different sizes, and screen same for the treatment of many types of cancer recited in the claim, the lack of direction/guidance presented in the specification, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that zeolites have different forms and sizes and most of those are used in industries, and the breadth of the claim which encompasses all types of zeolites without any structural limitations for treating all types of cancer, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

### ***Conclusion***

**NO CLAIM IS ALLOWED.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph. D.  
January 17, 2007

*Eileen B. O'Hara*  
EILEEN B. O'HARA  
PRIMARY EXAMINER